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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,934	06/24/2003	Baskaran Chandrasekar	201267.90011	1854

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EXAMINER	
COTTON, ABIGAIL MANDA	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,934	CHANDRASEKAR ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2003 and 05 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/088,405.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/24/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 9-14 are pending in the application as of the preliminary amendment filed on June 24, 2003.

Priority

Applicant's claim of foreign priority to CANADA 2,282,982 09/21/1999 and CANADA 2,300,246 03/09/200 is acknowledged.

Applicant's claim of domestic priority to co-pending U.S. Patent Application No. 10/088,405, filed July 24, 2002, is also acknowledged. However, the Examiner respectfully notes that the instant application appears to be a *continuation* or *continuation-in*-part of the prior case, and not a *divisional* of the case, as claimed by Applicant. A divisional application is a later application for a distinct or independent invention that is "carved out" of a pending application via a restriction requirement, and that discloses and claims only subject matter disclosed in the earlier or parent application. No restriction requirement has been made in the 10/088,405 parent case, and thus the claims presented in the instant case are not those that have been "carved" out of the parent. Accordingly, the appropriate relationship between the instant and parent case is that of a continuation or continuation-in-part case.

Appropriate correction and/or clarification of the application priority claim is required.

Specification

The specification is objected to in the cross-reference section on page 1, because the instant case is incorrectly referred to as being a divisional of the 10/088,405 parent case, when in fact the appropriate relationship is as a continuation or continuation-in-part of the parent case (see explanation above.) Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, claim 9, from which claims 10-14 depend, recites the limitation of "reducing restenosis by at least 50%", which is not

described or supported in the specification as originally filed. Appropriate correction and/or clarification is required.

Furthermore, the disclosure of the prior-filed application, Application No. 10/088,405, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. In particular, claim 9 and the claims depending therefrom are not adequately supported by the earlier-filed application because earlier application does not provide support for a method for "reducing restenosis by at least 50%," as recited in claim 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being obvious over the article entitled "17Beta-Estradiol Inhibits Proliferation and Migration of Human Vascular Smooth Muscle Cells: Similar Effects in Cells from Postmenopausal Females and Males" by Dai-Do et al, Cardiovascular Research 32 (1996) 980-985.

Dai-Do et al. teaches that postmenopausal women receive estrogen replacement therapy, and that 17Beta-estradiol is believed to protect women against vascular disease (seepage 981, first full paragraph, in particular.) Dai-Do et al. teaches that studies with 17Beta-estradiol show that it inhibits growth-factor-induced SMC proliferation, which provides cardiovascular protective properties against restenosis (see abstract, in particular.) Dai-Do et al. also teaches that PTCA is associated with restenosis, and thus teaches that restenosis follows vascular injury caused by PTCA (see Introduction, in particular.) Thus, Dai-Do et al. teaches that a women (or man) receiving 17Beta-estradiol, for example via hormone replacement therapy, has reduced restenosis, such as restenosis that might otherwise occur after vascular injury caused by PTCA.

Dai-Do et al. does not specifically teach reducing restenosis by at least 50% by administering an effective dose of 17-Beta estradiol.

However, as Dai-Do et al. clearly teaches that 17Beta-estradiol is effective in reducing restenosis, one of ordinary skill in the art at the time the invention was made would have been motivated to provide 17Beta-estradiol to a patient that has suffered vascular injury, and is thus at risk for and/or is experiencing restenosis, with the expectation of providing an appropriate treatment for the condition. One of ordinary skill in the art would furthermore have been motivated to optimize the dosage amount, dosage schedule, etc, of the 17Beta-estradiol, as known to those of ordinary skill in the

art, to provide the recited reduction of the restenosis of at least 50%. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Accordingly, the invention as recited in claim 9 is obvious over the restenosis reduction teachings of Dai-Do et al.

Claims 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No 5,866,561 to Mark T. Ungs, issued February 2, 1999.

Ungs teaches a method for inducing angiogenesis in blood vessel proximal to stenosed regions including application of an estrogen compound to the blood vessel wall proximal or upstream of the stenosis (see abstract, in particular.) Ungs teaches that PTCA often causes restenosis (see column 1, lines 10-20, in particular), and that administration of estrogen to the stenosed region after PTCA has been suggested for the purposes of preventing restenosis (see column 1, lines 40-50, in particular.) Ungs teaches that a preferred estrogen compound for administration includes 17Beta-estradiol (see column 4, lines 10-12, in particular.) Accordingly, Ungs teaches administration of an amount of 17Beta-estradiol to a patient having received PTCA, and thus having suffered vascular injury, to reduce restenosis.

Ungs does not specifically teach that the method reduces restenosis by the specific amount of at least 50% that is recited in the claim. However, as Ungs clearly

teaches that 17Beta-estradiol is effective in reducing restenosis, one of ordinary skill in the art at the time the invention was made would have been motivated to provide 17Beta-estradiol to a patient that has suffered vascular injury, and is thus at risk for and/or is experiencing restenosis, with the expectation of providing an appropriate treatment for the condition. One of ordinary skill in the art would furthermore have been motivated to vary and/or optimize the dosage amount, dosage schedule, etc, of the 17Beta-estradiol, as known to those of ordinary skill in the art, to provide the recited reduction of the restenosis of at least 50%. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Accordingly, the invention as recited in claim 9 is obvious over the restenosis reduction teachings of Ungs.

Regarding claim 10, Ungs teaches an embodiment in which the estrogen is carried by an ionic carrier (see column 2, lines 32-40, in particular.) Regarding claims 11-12, Ungs teaches the estrogen compound can be administered via a drug delivery balloon catheter (see column 2, lines 16-40, in particular.) Regarding claim 13, Ungs teaches that the estrogen compound can be administered by coating a balloon envelope with the compound, and advancing to the treatment site (see column 2, lines 26-32, in particular.) Thus, Ungs teaches administering the dose only once via a coated balloon envelope.

Regarding claim 14, Ungs teaches that the promotion of endothelial growth is a desirable part of wound healing after PTCA (see column 1, lines 30-40, in particular.) Thus, as Ungs teaches that the 17Beta-estradiol compound is capable of reducing restenosis, it is considered that administration of the compound as taught by Ungs must also improve reendothelization and vascular endothelium function, as Ungs administers the same compound as that being claimed. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to optimize the dosage of 17Beta-estradiol to provide the desired restenosis reduction and healing of the injured site, and the resulting improvement in vascular endothelium function and reendothelization. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Accordingly, claims 9-14 are obvious over the teachings of Ungs.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 8:30-5:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER